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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,357	12/04/2003	Tracy Doucette	03217/3762-001 US	6375

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,357	DOUCETTE ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the First Action on the Merits filed on June 28, 2005, is acknowledged.

Claims 1-8 are amended. Claims 9-20 are withdrawn following an election without traverse to a Restriction Requirement (see First Action, March 29, 2005).

Claims 1-8 are under consideration.

Withdrawn Rejections

35 U.S.C. § 112, 2nd parag.

Applicant's arguments, see pages 10-11 of Applicant's response, filed June 25, 2005, with respect to rejections under 35 U.S.C. § 112, 2nd parag. with regards to claims 1-8 have been fully considered and are persuasive. The rejection of claims 1-8 has been withdrawn.

With regards to the rejection of the term "reproducible," Applicant has overcome the rejection as the term "reproducible" has been deleted from claim 1.

With regards to the rejection of the terms, "mild" and "moderate," in claim 1, which are used to describe the type of stressor that induces a seizure, the Applicant points out that "mild" and "moderate" stressors are well known in the art and have indicated two journal articles that indicate what "mild" and "moderate" psychological stressors are. The Examiner finds the argument that use of "mild" and "moderate" stressors are art accepted terms and withdraws the rejection.

With regards to the rejection of claim 1 over the indefinite term, "low," Applicant has amended the claim to "subconvulsive" (Applicant's response, page 8). This overcomes the Examiner's rejection that the term was relative and indefinite. The Applicant also points out that the specification enables an artisan to practice the claimed invention for doses of 5 and 20 ug/kg domoic acid and 25 and 100 ug/kg of kainic acid, as described in Examples 1 and 2 of the specification. Therefore, the dose of 5 ug/kg of domoic acid are enabled (claims 5 and 6). With regards to using the doses of 10 or 20 ug/kg of kainic acid, these doses are not enabled and will be discussed in the New/Maintained Rejections section, below.

With regards to the issue of the use of the term "permanent" on page 16 of the Office Action, "permanent" was not a rejection. Page 16 was inadvertently included in the Office Action. The Examiner thanks the Applicant for addressing the issue and further clarifying characteristics that demonstrate that the neurological changes in the claimed invention is permanent (Applicant's response, page 11).

New/Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 and have further defined the term "kainate receptor agonist" as a "systematically bioavailable kainate receptor agonist" (Applicant's response, page 8). New matter has been introduced with regards to using the term, "systematically bioavailable." In addition to the Applicant not indicating where support in the specification is provided for this term, nothing in the specification teaches that the claimed invention is practiced with this limitation of kainate receptor agonist, nor is "systemically bioavailable" a term well known in the art.

The rejection for claims 1-4, 7, and 8 are maintained in part under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a method of inducing a permanent change in the neurological development of a rat, comprising treating a rat during the second postnatal week, with doses of 5 ug/kg to 20 ug/kg of domoate and doses of 25 ug/kg to 100 ug/kg of kainate, wherein the rat exhibits seizure-like symptoms upon exposure to a mild or moderate stressor that would normally not elicit a seizure,

does not reasonably provide enablement for

a method of treating a rat during the second postnatal week with any doses of any kainate receptor agonist, wherein the rodent exhibits seizure-like symptoms upon exposure to mild of moderate stressor that would not normally elicit a seizure.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for reasons of record stated in the Office Action, March 29, 2005.

Applicant's arguments, see pages 7-10 of Applicant's response, filed June 25, 2005, with respect to rejections under 35 U.S.C. § 112, 1st parag. with regards to claims 1-8 have been fully considered and are persuasive in part. The rejection of claims 1-8 has been withdrawn in part, as follows:

With regards to the rejection regarding "treatment of a rodent" (Applicant's response, page 7), Applicant has narrowed the scope of "rodent" to "rat." This overcomes the Examiner's rejection regarding the scope of the animal model.

With regards to rejection regarding frequency and duration of dosing age at which animals receive treatment (Applicant's response, page 9-10), Applicant has amended the claims. Applicant has included frequency of treatment and has included that the rats exhibit seizure-like symptoms following the period of treatment.

With regards to the dosage units (Applicant's response, page 10), Applicant has amended the claims to "ug/kg." The Examiner agrees that this was an inadvertent error and that the amended dosage units in the claims are now in agreement with what was taught in the specification.

With regards to the issue of whether an artisan is enabled for the use of the multiple forms of domoic acid (as two forms appear in Sigma and Fluka catalogs) (specification, page 10), the Applicant points out that these are different illustrations of

the same chemical. Further, the Applicant points out that different methods are used to isolate and purify the domoic acid from the biological source and thus the compounds are listed separately. Because the Applicant has pointed out that these two forms are the same compound, the Examiner finds the argument convincing and the specification is thus enabled for both forms of domoic acid.

Applicant's arguments, see pages 7-10 of Applicant's response, filed June 25, 2005, with respect to rejections under 35 U.S.C. § 112, 1st parag. with regards to claims 1-8 have been fully considered and are not persuasive for the reasons discussed below. Thus, the rejection with regards to these issues remains.

With regards to the route of administration, claims 1-4 broadly encompass any route of injection. As stated on pages 6-7 of the Office Action of March 29, 2005, while the specification and art teach intraperitoneal and subcutaneous injection of domoic acid and kainic acid, the art does not teach other routes of injection. It should be pointed out that in the concluding statement of the scope of enabled routes of injecting domoic acid and kainic acid that the Examiner had inadvertently stated that intravenous was enabled. This is incorrect; the scope was intraperitoneal and subcutaneous. Despite this, the enablement issue regarding administration of a drug involved an artisan needing to know how quickly a drug is absorbed, how quickly does the drug take to get to the site of interest, and how quickly does the drug leave the site of interest. While the specification and art teach intraperitoneal and subcutaneous, the specification does not teach an artisan how to reliably administer domoic acid and kainic acid by other injection routes such that an artisan would predictably arrive at the claimed

invention. For this reason, the claimed invention is limited to intraperitoneal and subcutaneous.

With regards to the scope of using any kainate receptor agonist (Office Action, March 29, 2005, pages 8-9), the primary point of the rejection was that the genus of "kainate receptor agonist" broadly encompasses a variety of compounds which, while "agonists," have different biological effects. Particularly in the example cited by the Examiner, APTA, this compound is a kainic acid receptor agonist, but prevents the propagation of seizures from one hemisphere to the other. The art of record illustrates that not all kainate receptor agonists could predictably be used to generate the claimed invention.

With regards to the scope of dosages of kainic acid that are used to generate the claimed invention, the specification teaches that the claimed invention can be obtained by using dosages of 25 ug/kg to 100ug/kg (Office Action, March 29, 2005, pages 5-6). The Applicant further confirms this range of dosages, by stating that "positive testing results for 25 ug/kg and 100 ug/kg of kainic acid are provided for male and female rats in Example 3 (Applicant's response, page 9)." However, the specification does not predictably teach that lower dosages of 10 or 20 ug/kg of kainic acid can be used to generate the claimed invention (claims 7 and 8). The Examiner had indicated in the previous Office Action (March 29, 2005) that the specification has not taught that doses less than 25 ug/kg of kainic acid could be used to generate the claimed rats (page 6, lines 6-9). Applicant has not traversed this issue. Therefore, the rejection regarding the dosages stated in claims 7 and 8 stands.

Claim 1 is further rejected for lack of enablement, resulting from the amendment to the claims. Claim 1 reads such that the claimed invention is obtained by using a minimal dose of 5 ug/kg of any kainate receptor agonist. Claim 1 can be read that an artisan can obtain the claimed invention by using 5 ug/kg of kainic acid. However, as stated in the previous paragraph, no guidance was provided whether an artisan can arrive at the claimed invention using doses less than 25 ug/kg.

It is noted that Applicant has stated that claim 8 has been amended to specify 25 to 100 ug/kg kainic acid (Applicant's response, page 9), rather than 20 to 50 ug/kg kainic acid. However, no amendments to claim 8 with regards to dosage has been made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 5 uses the phrase, "said does being a minimum." This phrase is unclear and appears to be a typographical error. The Examiner suggests that "doses" be substituted for "does."

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

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PRIMARY EXAMINER